

## **INTELLECTUAL PROPERTY APPELLATE BOARD TO HEAR THE NOVATIS CASE**

Praveen Raj

The infamous Novartis Patent Case transferred to Intellectual Property Appellate Board (IPAB), Chennai by the Madras High Court following an order by the division bench comprising Justice R. Balasubramanian and Justice Prabha Sridevan on April 4 comes for hearing before IPAB on June 18. Even though IPAB was set up on 15th September 2003, it has become fully functional to hear the appeals against Controller of Patents only after Shri S. Chandrasekaran assumed the charge of the post of Technical Member (Patents), of Intellectual Property Appellate Board (IPAB) following a Government Order dated 2nd April, 2007. The appeal against the decision of Shri. V. Ranagaswamy, Assistant Controller of Patents & Designs, rejecting a Patent for beta-crystalline form of imatinib mesylate - a polymorphic form likely used is marketed formulation of Novartis's blockbuster anticancer drug Gleevec will now be heard by a division bench of IPAB comprising its Chairman, Justice Mr M.H.S. Ansari, and the technical member Mr S. Chandrasekaran. Even though the appeal against the decision of the Controller stands transferred to IPAB according to section 117G of the Patent Act, the Madras High Court will continue to proceed and deal with the constitutional validity of Section 3 (d) of the Patents Act, 1970. The judgment by Madras High Court in this respect is expected on 19th June 2007.

Even though the Appellate Board will likely to decide the merit of the patentability of beta-crystalline form of imatinib mesylate under the Patents Act, 1970, it is still need to be seen that whether Appellate Board will proceed with the matter either de novo or from the stage where the Madras High Court had left. It is also worth mentioning here that here is no provision in the concerned statute for any further appeals from the decision of the IPAB. However, as per decisions of the Supreme Court of India, this would not prevent an aggrieved party from seeking a writ remedy in the appropriate High Court. Domestic drug-makers such as Natco, Cipla, Hetero and Ranbaxy, besides patient-organisations like the Cancer Patients Aid Association who had opposed Novartis' patent application at the Patent Controller's office has been allowed as respondents to the case filed by Novartis at the High Court, and which stand transferred to IPAB, Chennai. The transfer of the case to the IPAB worries the Swiss drug-maker Novartis as the board comprised Mr Chandrasekaran, the former Controller General of Patents, who was the head of the Patent Office when Novartis' patent application on Glivec was rejected by Patent Office.

Novartis had appealed the before Madras High Court against Asst Controller of Patents and Designs' order of January 25, 2006 invalidating its patent application for the beta crystalline form of Glivec (imatinib mesylate). Novartis had also asked the court to declare section 3(d) of the Patents

Act, 1970 as amended in 2005 as unconstitutional and in breach of India's obligation under the TRIPS agreement. The Controller's decision was based on the following.

1. It is not new (it is anticipated from a 1992 patent application covering the Imatinib base)
2. It is a salt form that does not demonstrate an "increased efficacy" over the earlier known Imatinib base and hence is unpatentable under section 3 (d).

Mr. V. Rangaswamy while giving in his judgement made the following observations.

'I do not agree with the contention of the Applicant that the 1993 patent discloses only the free base. The 1993 patent discloses methanesulphonic acid as one of the salt forming groups and also the 1993 patent specification states that the required acid additions salts are obtained in a customary manner. Further, claims 6 to 23 of the 1993 patent claim a pharmaceutically acceptable salt of the base compound. The patent term extension certificate for the 1993 patent issued by the US Patent Office specifically mentions imatinib mesylate (Gleevec) as the product. All these points clearly prove that imatinib mesylate is already known from the prior art publications.' He Further stated - "As per the affidavit the technical expert has conducted studies to compare the relative bioavailability of the free base with that of crystal form of imatinib mesylate and has said that the difference in bioavailability is only 30% and also the difference in bioavailability may be due to the difference in their solubility in water."

Section 3(d) provides that the following will not be considered as an invention

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant,

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy

The IPAB's verdict on "patentability" will depend on whether or not they are convinced that Imatinib Mesylate was in fact 30% more "bio-available" than the other forms and therefore more "efficacious" under section 3(d). If this is not factually correct, then the IPAB may uphold the decision of the

Controller rejecting the patent. Unfortunately, the order of the Controller in this regard is not very comprehensive. From the order, it appears that the Controller was not convinced, as a matter of fact, that this salt form was, in fact, 30% more bio-available and hence more efficacious.

According to Mr. R.S. Praveen Raj, an IPR Expert - Section 3(d) can also be interpreted such that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall not be considered to be the same substance if they differ significantly in properties with regard to efficacy. Now comes the question of definition for 'efficacy', which is not found referred in any other patent statute in the world. In the absence of a definition for 'efficacy', attorneys of MNCs can conveniently interpret it to their advantage and get the protection, which they seek. In effect are we stopping ever greening or facilitating it?

Mr. Raj adds further that the invention of Novartis is not Novel or Non-obvious. He says " In this connection I would like to put forward a billion-dollar question to the R & D managers of the Indian pharmaceutical companies - Was it not possible to find at least ten documents falling in the International Patent Classification (6) A61K 031/506 and C07D 401/14 to attack the novelty and non-obviousness of the alleged invention (especially when the priority of CH1764 dated 18/07/1997 was not applicable in India as Switzerland was not a convention country at the time making the patent application)"

While IPAB starts hearing the appeal on the Assistant Controllers' Decision, the Final Judgement by Madras High Court on a Petition filed by Novartis on 17 May, 2006, challenging two distinct elements: the grounds on which the Indian patent office, led by the Patent Controller, rejected the patent, and separately, a section of India's patent law that formed the basis of the patent office decision, which Novartis said not only contravenes TRIPS but Article 14 of the Indian Constitution, which ensures equality before the la, is expected on 19/06/07.

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